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09/669,051	09/24/2000	Nicolas F. Franano	55225	2612

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/669,051

**Applicant(s)**

FRANANO, NICOLAS F.

**Examiner**

Dr. Kailash C. Srivastava

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>0217</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

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### **DETAILED ACTION**

1. Applicants' amendment and response filed 12/15/2002 to Office Action mailed July 25, 2003 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-55 have been cancelled.
3. Claims 56-60 have been amended.
4. Claims 61-68 have been added.
5. Claims 56-68 are pending and are examined on merits.

### **Objection to Information Disclosure Statement**

6. The Supplemental information disclosure statement filed 12/15/2003 fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered, except for those cited on PTO-892.
7. Applicant's Supplemental Information Disclosure (i.e., IDS) filed July 03, 2003 is objected to because in Office Action mailed July 25, 2003 applicant was required to submit a legible copy of the citation "AL", Curci, J.A. et al., Journal of Vascular Surgery, February 1999, Volume 29 (2), Pages 1-3. Said reference has not been enclosed in response to said Office Action.

### **Claims Objection**

8. Claims 59-60 objected to because of the following informalities: Claims are dependent on a non-preceding claim. Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 112***

9. Following is a quotation of the second paragraph of 35 U.S.C. § 112:

***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

10. Amended Claims 56-60 and newly added claims 61-68 dependent upon Claim 56 stand under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - The phrase "susceptible to obstruction" renders Claim 56 vague, unclear and confusing. The phrase is vague because any artery or vein or for that matter a biological conduit can become

obstructed during the lifetime of the organism in which said conduit is present. Furthermore, with this phraseology, Claim 56 gives the connotation of a preventive method. Inventions targeted for human therapy claiming method(s) of prevention of a certain ailment bear a heavy responsibility to provide supporting evidence because of the unpredictability of the biological responses to therapeutic treatments, because effective prevention or prophylaxis of disease conditions are relatively rare, and may be unbelievable in the absence of supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to human that would in effect "prevent" the condition/ailment from happening require supporting evidence because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis.

- Phrase "an agent comprising" renders Claims 56-59, 61 and 67-68 vague, unclear and confusing. Examiner suggests that the applicant replace said phrase with the phrase "a composition comprising".

All other claims depend directly from the rejected Claim 56 and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### ***Claim Rejections Under 35 U.S.C. § 102***

11. Amended Claims 56-57 stand rejected under 35 U.S.C. §102(b) as anticipated by Anidjar et al. (Annals of Vascular Surgery, 1994. Volume 8, Pages 1128-136).

Anidjar et al. teach administering pancreatic elastase to rat aorta. Subsequent to treatment, aorta diameter and aneurysm were significantly increased (Abstract, Lines 2-23). Please note that the prior art reference inherently anticipated the claims as drafted (i.e., Claims 56-57), because the reference teaches per fusing aorta in a living animal with a composition comprising elastase to enlarge the aorta lumen and therefore, inherently teaches treating an artery or vein "susceptible to obstruction" via administering an elastase to the wall of said aorta. Thus, the prior art method inherently teaches claimed invention because the prior art method is administering same material to an artery or vein that is susceptible to obstruction to enlarge its lumen as is recited in the claimed invention.

Therefore, the reference is deemed to anticipate the cited claim.

12. Amended Claims 56-57 stand rejected under 35 U.S.C. §102(b) as anticipated by Ooyama et al. (The Molecular Biology and Pathology of Elastic Tissues. 1993. Wiley Chichester, Pages 307-320).

Ooyama et al. teach administering an "anti-atherosclerotic drug containing porcine pancreatic elastase I (PPEI)" to treat atherosclerosis in elderly patients. In patients receiving said drug, the

atherosclerotic index is lowered (Abstract, Lines 2-23) and the intima-media thickness of the carotid artery is reduced (Page 314, Lines 12-14 underneath the Figure 6). Please note that the prior art reference inherently anticipates the claims as drafted (i.e., Claims 56-57) because the reference teaches administering a composition comprising elastase to reduce thickness of artery wall (i.e., enlarge the arterial lumen) in human subjects and therefore, inherently teaches treating an obstructed artery or an artery "susceptible to obstruction" via administering elastase to the wall of said artery. Thus, the prior art method inherently teaches claimed invention because the prior art method is administering same material to an artery that is susceptible to obstruction to enlarge its lumen as is recited in the claimed invention.

Therefore, the reference is deemed to anticipate the cited claim.

### ***Claim Rejections Under 35 U.S.C. § 103(a)***

13. Claims 56-60 and newly submitted claims 61-68 dependent on Claim 56 stand rejected under 35 U.S.C. § 103 (a) as obvious over Anidjar et al. (Annals of Vascular Surgery, 1994, Volume 8, Pages 1128-136) and Ooyama et al. (The Molecular Biology and Pathology of Elastic Tissues, 1993, Wiley Chichester, Pages 307-320) in view of Strindberg et al. (Journal of Investigative Surgery, 1998, Volume 11, Pages 185-198).

Teachings from Anidjar et al. and Ooyama et al. have already been discussed *supra*. These references do not teach administering collagenase, or compositions comprising a mixture of elastase and collagenase or administering said compositions via catheter.

Strindberg et al. beneficially teach administration of either elastase by itself or in combination with collagenase or with catheter to enhance aneurysm in dogs whose aortas were in-vivo profused with said compositions. Furthermore, said treatments also showed hyperplasia (Abstract, Lines 6-25). Thus, the prior art methods intrinsically render the claimed invention obvious because each one of Anidjar et al., Ooyama et al., and Strindberg et al. teach a method to enlarge arterial aneurysm under in-vivo conditions in an animal via administering to said animal a preparation comprising either elastase, or a combination of elastase and collagenase. Since the prior art references teach methods to administer same compositions according to same methods comprising same steps to treat either an obstructed or "susceptible to obstruction" artery or vein as the instantly claimed invention; the prior art references intrinsically teach methods to treat an obstructed or "susceptible to obstruction artery or vein" in an animal, wherein said animal is a human subject and since stenosis or coronary obstruction or intimal hyperplasia are different types of cardiovascular obstructions, the teachings from referenced prior art teach a method to treat an obstructed or "susceptible to obstruction artery or vein" in a human subject via administering a composition comprising elastase or mixture of elastase and collagenase.

Thus, an artisan of ordinary skill at the time that said invention was made would be motivated to combine the teachings from each one of the cited prior art references to obtain a method to treat in-vivo an obstructed or "susceptible to obstruction artery or vein" in a subject via administering to said subject a composition comprising either elastase, collagenase, or a mixture of elastase and collagenase. While Ooyama et al. remedy the deficiency of treating an obstructed or a susceptible to obstruction human artery or vein in the teachings from Anidjar et al., Strindberg et al., remedy the deficiency of treating said condition in a subject with a mixture of collagenase and elastase,

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition and method of anidjar et al., according to the teachings from Ooyama et al., and Strindberg et al., because all of the prior art references teach treating under in-vivo condition in a subject an obstructed or "susceptible to obstruction artery or vein". Ooyama et al. remedy the deficiency of treating an obstructed or a "susceptible to obstruction human artery or vein" in the teachings from Anidjar et al. and Strindberg et al. remedy the deficiency of treating said condition in a subject via administration with or without a catheter, a mixture of collagenase and elastase.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

## CONCLUSION

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. No Claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner

can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571)-272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(571) 272-0923

February 24, 2004



CHRISTOPHER R. TATE  
PRIMARY EXAMINER